REMARKS

Status of the Claims

Claims 1-4 are currently pending in the application. Claims 1-6 stand rejected. Claims 1-6 have been amended as set forth herein. Claims 5 and 6 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to the claims are clarifying amendments that are directed at more clearly stating Applicant's invention. Other amendments to claim 1 regarding exogenous feeder cells is supported in the as-filed specification at, for instance, pages 6-7. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-6 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. (*See*, Office Action of April 21, 2006, at page 2, hereinafter, "Office Action"). Claims 5 and 6 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 5 and 6. Applicant traverses the rejection as to the remaining claims as set forth herein.

The Examiner states that claim 1 is vague because "it is confusing what the claims encompass." Although Applicant does not agree that claim 1 is vague and/or indefinite, to expedite prosecution, claim 1 has been amended to recite, "A method of producing human chondrocytes , wherein said method comprises: co-culturing chondrocytes together with perichondrium, wherein said chondrocytes are obtained from a cartilage having said perichondrium, and wherein no

exogenous feeder cells are present in the culture." Thus, as amended, claim 1 is clearly directed to a method of producing human chondrocytes involving co-culturing chondrocytes with perichondrium wherein the perichondrium and chondrocytes originate from the same tissue and wherein no exogenous feeder cells are added to the co-culture.

Since no specific reasoning is provided for the rejection of dependent claims 2-4, claims 2-4 are believed to not be indefinite for, *inter alia*, depending from a definite base claim, independent claim 1.

Reconsideration and withdrawal of the indefiniteness rejection of claims 1-4 are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hiroko et al, WO 02/012451, corresponding to EP 1331264 (hereinafter Hiroko et al.). (*See*, Office Action, at page 2). Claims 5 and 6 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 5 and 6. Applicant traverses the rejection as to the remaining claims as set forth herein.

The Examiner states that Hiroko et al. disclose a method of co-culturing human chondrocytes together with perichondrial cells and further disclose a cartilage therapy material incorporating a chondrocyte mass obtained by the method. (*Id.*).

Claim 1 recites, "A method of producing human chondrocytes , wherein said method comprises: co-culturing chondrocytes together with perichondrium, wherein said chondrocytes are obtained from a cartilage having said perichondrium, and wherein no exogenous feeder cells are

present in the culture." Thus, as amended, claim 1 is clearly directed to a method of producing human chondrocytes involving co-culturing chondrocytes with perichondrium wherein the perichondrium and chondrocytes originate from the same tissue and wherein no exogenous feeder cells are added to the co-culture. Claim 1 specifically precludes the presence of exogenous feeder cells from the co-culture method.

In contrast, Hiroko et al. do not disclose co-culturing of chondrocytes with perichondrium obtained from the same tissue and wherein the co-culture method is performed without any exogenous feeder cells. The method disclosed by Hiroko et al. requires the presence of exogenous feeder cells, perichondrial cells, to support the proliferation method. The perichondrial cells of Hiroko et al. are disclosed at, for instance, paragraphs [0017]-[0022]. In various cell culture techniques, exogenous feeder cells are used to supply essential growth factors. However, when cells are to be used for transplantation, the presence of such exogenous growth factors can be problematic.

The presently claimed method is capable of proliferating chondrocytes using only the perichondral cells obtained during sample collection. (*See*, specification, at pages 6-7). This is an important advance in the art.

Thus, since Hiroko et al. do not disclose each and every element of the presently claimed invention, as recited in claim 1, Hiroko et al. cannot anticipate the presently claimed method.

Dependent claims 2-4 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1-4 are respectfully requested.

Rejections Under the Obviousness-Type Double Patenting Doctrine

Claims 1-6 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable by co-pending U.S. Patent Application No. 10/344,135 (hereinafter, "the '135 application"). (*See*, Office Action, at page 4). Claims 5 and 6 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 5 and 6. Applicant traverses the rejection as to the remaining claims as set forth herein.

The present rejection is provisional. Thus, Applicant will wait until allowable subject matter has been identified in the co-pending application. (*See*, M.P.E.P. § 804(B)(1)). However, to further assist prosecution of the present application, Applicant provides the following remarks to showing that the pending claims in the '135 application are patentably distinct from the present claims.

Claim 15 of the '135 application recites, "A method for culturing human chondrocytes, comprising co-culturing human chondrocytes with feeder cells, thereby increasing the proliferation of said chondrocytes, and wherein said feeder cells are perichondral cells in the chondrogenic stage and the proliferation ability of said feeder cells is eliminated before co-culturing." The "perichondral cells in the chondrogenic stage" means that the perichondral cells are in embryogenesis and that the proliferation ability of the cells is eliminated before co-culturing, as is recited in claim 15. Furthermore, the perichondrium is not formed during the culturing process. Thus, the perichondral cells must be obtained from a source which is in embryogenesis. European patent EP 1331264, the counterpart of the '135 application, discloses in the specification at paragraph [0008] that the feeder cells are "chondrogenic-stage

perichondral cells from a mammalian fetus," and they are especially "chondrogenic-stage perichondral cells from a 13-day-old murine fetus." Thus, the methods of the '135 application are clearly different from the presently claimed methods.

Reconsideration and withdrawal of the provisional obviousness-type double patenting rejection of claims 1-4 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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